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USE OF COMPRESSION CLIPS MADE OF SHAPE MEMORY MATERIAL IN THE GASTROINTESTINAL SURGERY – A PRELIMINARY REPORT

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The aim of the study was to present a clinical use of compression clip (CC) implants made of shape memory materials, i.e., superelastic nickel titanium alloys (NiTi). This report represents the first experience with these materials in gastrointestinal surgery in Poland.
Material and methods. Nine anastomoses were performed in 8 patients using CC: Two anastomoses of the small intestine with the large intestine, 3 anastomoses of the small intestine with the small intestine, 3 anastomoses of the stomach with the small intestine, and 1 anastomosis between the transverse colon and the duodenum.
Results. No complications related to this method were observed. Delayed clip excretion was found in one patient. (On day 61 after the surgery, radiological imaging showed that the clip was located in the rectum.)
Conclusions. A preliminary study investigating the use of compression clips made of shape memory TiNi alloys in gastrointestinal anastomoses demonstrated that they led to safe anastomoses. Because only a small number of anastomoses have been performed by us to date, this procedure requires further study.
Key words: compression clips, NiTi, shape memory, anastomoses

Mechanical suture is a common and accepted technique for gastrointestinal anastomoses. It reduces the duration of the surgical procedure, leading to a generally leakproof, reliable anastomosis. Mechanical suture appliers were launched in the 1950s, although the idea itself is much older. The first known mechanical anastomosis device was made by Denans in 1826. The same concept underlies ideas by Bonier in 1885 and Murphy in 1892 (1-4). These methods were quickly forgotten, and the idea of mechanical suture was abandoned for many decades. The idea of mechanical anastomosis was revived in the mid-1980s by Hardy et al. (5, 6). Biofragmentable Valtrac rings are based on his concept. They undergo degradation or, less often, are excreted intact from the gastrointestinal tract. Currently, the most common mechanical suture used for gastrointestinal anastomoses is mechanical stapled suturing (circular or linear).

Anastomosis leakage is the most common cause of complications and mortality in the postoperative period in the gastrointestinal surgery. In the late postoperative period, the surgeon's efforts are diminished by constriction at the anastomosis site. Thus, searching for new anastomosis techniques that prevent the occurrence of complications is warranted.

The aim of our study is to present the first experience in Poland of the clinical use of compression clip (CC) implants made of shape memory materials, i.e., superelastic nickel titanium alloys (NiTi), in gastrointestinal surge-

ry. These alloys are an important part of the development of new medical technology worldwide. Shape memory phenomena are closely related to a reversible martensitic transformation that is accompanied by structural changes (change of special atom distribution) during cooling or heating at a specified temperature or as a result of application or removal of an external stress (7, 8). This means that the martensitic transformation in NiTi alloys is both reversible and thermoelastic (7, 8).

The unique characteristics of shape memory and superelasticity, in particular, high resistance to corrosion and biological absorbability of NiTi alloys by tissues, are utilized in the manufacturing of various implants and medical instruments (7, 9, 10). These implants are currently used in orthopedic, neurological, cardiac, vascular, maxillary, and gastrointestinal surgery (7, 8, 10-15).

Our study utilized an implant in the form of elliptic bispiral rings made of a NiTi alloy using the shape memory effect. An anastomosis performed using the implant belongs to the class of so-called compression anastomoses. In the literature, this procedure is termed CAC (Compression Anastomosis Clip) (fig. 1) (6, 11, 12, 16). The principle of the clip's action involves a change of the clip's shape depending on the temperature. When it is placed in a cold water (approx. 0°C), its arms (coils) can be unbent by approx. 30-40° (11, 12, 16). Such unbent fragments are introduced to the parts of gastrointestinal tract that are to be anastomosed (fig. 2). At the temperature of human body, the clip reverts to its original shape, bringing the anastomosed walls nearer to each other. At the site when the walls make contact with each other, compression-induced ischemia and necrosis result within 5-7 days (11, 16). A scar is formed at the periphery of this necrosis, which forms the basis for a symmetric, well-functioning anastomosis. Within 5-16 days (depending on the site of its application), the clip is naturally excreted from the intestine with the stool (11, 16, 17).

Fig. 1. A compression clip

MATERIAL AND METHODS

After receiving Bioethics Committee approval, 9 first anastomoses were performed in 8

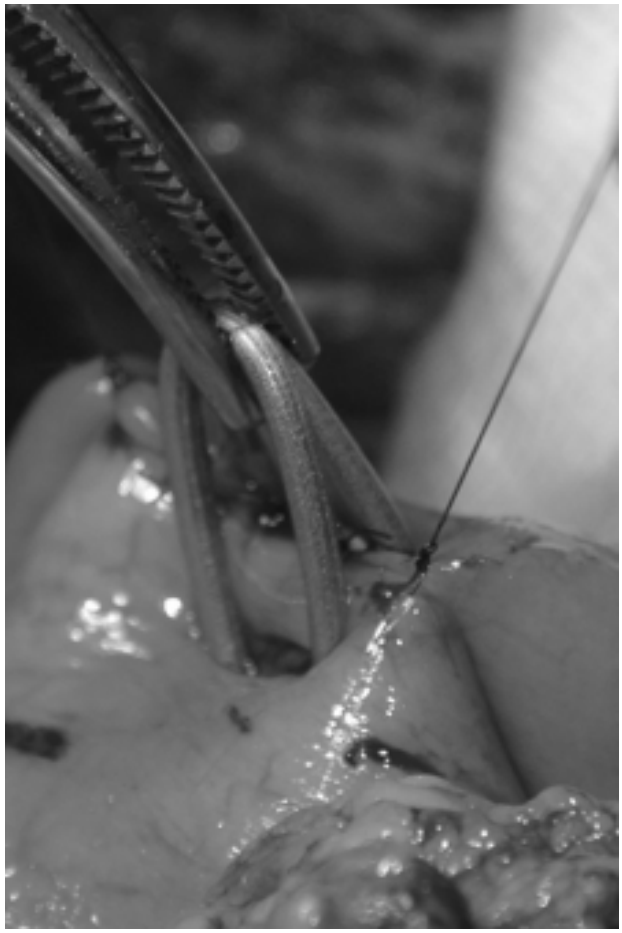

Fig. 2. Performance of an anastomosis between the stomach and the small intestine using a compression clip

patients in the Clinic of Surgery prior to November 2007 using a compression clip (CC). The anastomoses included 2 anastomoses of the small intestine with the large intestine, 3 anastomoses of the small intestine with the small intestine, 3 anastomoses of the stomach with the small intestine, and 1 anastomosis between the transverse colon and the duodenum. The patients, 4 women and 4 men, were between the ages of 48-77 years. The first patient underwent surgery for pancreatic cancer. Since the lesion was unresectable, a gastrojejunal bypass anastomosis was performed, side-to-side, using CC. The other two gastrojejunal anastomoses were performed in a patient with gastric cancer infiltrating the pancreas and in a patient with chronic pancreatitis. Another patient underwent surgery for cancer recurrence after a previous right hemicolectomy. The tumor originated from the extraperitoneal space and involved loops of the small intestine, which were resected. The anastomosis of the small intestine was done side-to-side, using a CC. Another anastomosis of the small intestine with the small intestine was done side-to-side between the part of the loop that harbored a previous anastomosis between the biliary tract and the intestine. The patient underwent surgery for cancer of Vater's ampulla and underwent Claget pancreatoduodenectomy. A similar anastomosis was performed in a patient during pancreatoduodenectomy for cancer of the pancreatic head. An anastomosis between the small and large intestine using a CC was performed in 2 patients. For the first patient, a bypass anastomosis, side-to-side between the small intestine and the transverse colon, was performed for intestinal obstruction following resection of the urinary bladder due to cancer. The procedure was of palliative nature due to tumor dissemination. The second anastomosis between the small intestine and the transverse colon was performed in a patient in whom gastrointestinal continuity was being restored after a previous esophageal and gastric resection due to cancer. The right half of the colon was used to create a substitute. A side-to-end anastomosis of the duodenum with the transverse colon was performed in the same patient.

The anastomosis technique involved making approx. 5 mm incisions on the anastomosed intestinal walls at the site of the predicted anastomosis. The CC was placed into water at approx. 0°C for a few minutes, enabling unbending of its arms by approximately 30-40°. The unbent CC was placed though the incisions into the apposed anastomosed intestines with each arm to a separate loop. At body temperature, the clip reverts to its original shape, pressing the anastomosed surfaces together. The incisions in the intestinal walls were closed with a continuous suture using PDS 4-0. After necrosis develops around the CC, the CC detaches from the intestinal walls and is excreted with the stool.

RESULTS

No complications related to this method were observed. Delayed clip excretion was found in one patient. (On day 61 after the surgery, radiological imaging showed that the clip was located in the rectum.)

DISCUSSION

Compression anastomosis has its own long history. Valtrack anastomosis is the most popular example. This type of anastomosis is based on a similar pathomechanism to CC anastomosis. A variable degradation time, high cost, and narrow inner lumen after the anastomosis are the drawbacks of biofragmentable anastomoses. Concurrently, interpretation of the typical sound that accompanies the correct "latching" of the rings and which is the basis for compression anastomosis is not always clear. TiNi alloys with shape memory provide continuous, homogenous pressure independent of surgical manipulation (11, 12, 16). TiNi alloys with shape memory are used all over the world; their use has been reported in Poland in maxillary surgery (10). In contrast to the stapler suture, the CC allows better control of mucosal matching, thus enabling a safer union of the anastomosed parts of the gastrointestinal tract, which is supported by histopathologlcal examinations (11). In contrast to the staples of the mechanical stapler, which are left in place, CCs are completely excreted from the gastrointestinal tract and do not disturb gastrointestinal function, leaving a larger lumen of the anastomosis and allowing for magnetic resonance imaging (11, 12, 16). A method that utilizes CCs is termed "fully no-touch" and is associated with a decreased incidence of postoperative complications (11). Use of CCs requires only a small area of opening of the intesti-

ne and thus reduces the risk of infection (lower contamination with intestinal bacteria). CC can be used with laparoscopic and endoscopic techniques to perform anastomoses between the stomach, small intestine, and large intestine (16, 17). The ease of CC application is associated with a shortened procedure duration, a shorter duration of anesthesia, and, thus, lower costs of the procedure. The lower cost of CC anastomoses (approx. $3 as compared to the costs of mechanical suture – $100) is equally important (5, 12, 16).

In our opinion, a significant technological advance includes the use of a cooled instrumentation set (Pean's forcepts and pincet) to apply the CC. Because the clip is clamped at the body temperature, due to the use of cooled instruments, we have more time to properly place the clip. In our study, we did not use preventive sectioning of the intestinal wall at the CC lumen, which, according to other authors, is supposed to enable transport of gases and liquid intestinal contents. We did not find any evidence of intestinal obstruction in the study population. Further studies are needed to solve this problem.

CONCLUSIONS

A preliminary study of shape memory compression clips made of a TiNi alloy used in gastrointestinal anastomoses demonstrated that this type of anastomosis is safe. Because only a small number of anastomoses were performed by us, further studies are required, although our conclusions are in agreement with conclusions presented in the foreign literature, which are based on the use of a much larger material. The easy and quick application of CCs and their low cost must be emphasized.

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